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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/686,491	10/14/2003	Rossella G. Tupler	07917-180001 / UMMC 03-18	3543

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EXAMINER	
STANDLEY, STEVEN H	

ART UNIT	PAPER NUMBER
1649	

DATE MAILED: 10/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/686,491	TUPLER ET AL.	
	Examiner	Art Unit	
	Steven H. Standley	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-22 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-22 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restrictions

1. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claim 8-21 been renumbered 9-22.

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-7, drawn to a method of identifying a molecule that binds a DNA D4Z4 binding element, classified in class 435, subclass 7.2.

II. Claims 8-9, drawn to a method of identifying a molecule that modulates expression of a D4Z4 recognition complex (which is a polypeptide such as nucleolin), classified in class 435, subclass 7.2.

III. Claims 10-11, drawn to a method of identifying a molecule that enhances the binding element/recognition complex (DNA-protein) interaction, classified in class 435, subclass 7.2.

IV. Claims 12-14, and 22 drawn to a method of determining whether a treatment for FSHD is effective, classified in class 424, subclass 9.1, or 800, subclass 3.

V. Claims 15-16, drawn to a method of treating a patient with a compound that increases expression or activity of at least one component of the D4Z4 recognition complex, classified in class 514, subclass 1.

VI. Claims 17-18, drawn to a method of identifying a subject having or at risk of having facioscapulohumeral muscular dystrophy (FSHD), classified in class 424, subclass 9.1.

VII. Claims 19-21, drawn to a non-human transgenic animal expressing at least one 4Q35 gene, classified in class 800, subclass 8.

Although there are no provisions under the section for "Relationship of Inventions" in the M.P.E.P. § 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute distinct inventions for the following reasons: Groups I-III are drawn to distinct methods of identifying molecules that could be of potential therapeutic value to FSHD because they recite different steps, use different products, and take different measurements. Group I is to a method of identifying compounds that interact with the DNA at a region designated as D4Z4, and it measures the binding of candidate compounds to D4Z4. Group II is to a method of identifying molecules that modulate the expression of a protein complex known to bind the D4Z4 region, called 'D4Z4 recognition complex,' and measures expression levels of the recognition complex. The two methods involve different steps and different physical products, and are very unlikely to identify the same kinds of molecules. Group III is to a method of identifying molecules that enhance recognition complex binding to D4Z4 and works by measuring

the binding between the recognition element and the DNA sequence. Thus, group III has different steps than group I or II, uses different products than group I or II, with the goal of identifying a compound that enhances an interaction, which is also different than group I or II. Therefore the methods do not share the same goals. Because the methods have different steps and use different products, a search and examination of both methods together would not be coextensive. Therefore a search and examination of the methods of group I, II, or III together or in any combination would constitute an undue burden, since the searches are entirely different and not coextensive, the classifications are different and the subject matter divergent.

Although there are no provisions under the section for "Relationship of Inventions" in the M.P.E.P. § 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute distinct inventions for the following reasons: groups I-III are each directed to methods distinct from the method of group IV, which is a method of determining whether a treatment for FSHD is effective. The goals of invention groups I-III are different from the goals from invention group IV, as well as different steps and different test systems. Group IV obtains a sample from a subject being treated, while groups I-III provide D4Z4 binding elements (I), or cells (II), or binding and recognition elements (III). Group IV measures 4Q35 *gene expression*, while groups I-III measure interaction of the test compound with D4Z4 (a DNA subregion of 4Q35), expression of the *recognition complex,* or binding between the D4Z4 and the recognition complex, which are all different measurements. Therefore a search and examination of the methods of group

I-III and group IV would constitute an undue burden, since the searches are entirely different and not coextensive, the classifications are different and the subject matter divergent.

Although there are no provisions under the section for "Relationship of Inventions" in the M.P.E.P. § 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute distinct inventions for the following reasons: groups I-IV are each directed to methods distinct from the method of group V, which is a method of treating a subject having FSHD.

The goals of invention groups I-IV are different from the goals from invention group V, as well as different steps and different test systems. Group V treats a patient for FSHD, while groups I-IV identifies molecules that affect binding to D4Z4 or expression of 4Q35 genes, or determine whether a treatment is effective. Groups I-IV have different steps from group V as well. Group V has the step of administering a compound to a patient, whereas group I provides D4Z4 binding element and tests a compound for binding, group II provides a cell expressing a D4Z4 recognition complex component and tests a compound, group III provides a D4Z4 binding ***and*** recognition element and tests a compound, and group IV obtains a biological sample from a subject and measures a 4q35 gene. Therefore a search and examination of the methods of group I-III and group IV would constitute an undue burden, since the searches are entirely different and not coextensive, the classifications are different and the subject matter divergent.

Although there are no provisions under the section for "Relationship of Inventions" in the M.P.E.P. § 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute distinct inventions for the following reasons: groups I-V are each directed to methods distinct from the method of group VI, which is a method of identifying a subject at risk for FSHD. The methods are directed to different goals, have different steps, and utilize different things. Group V administers to a patient with FSHD, Group IV obtains a sample from a subject being treated , while groups I-III provide D4Z4 binding elements (I), or cells (II), or binding and recognition elements (III). Group VI measures 4Q35 expression compared to controls and find subjects at risk, Group V treats a patient, Group IV measures 4Q35 *gene expression*, while groups I-III measure interaction of the test compound with D4Z4, expression of the *recognition complex,* or binding between the D4Z4 and the recognition complex, which are all different measurements and different goals. Therefore a search and examination of the methods of group I-V and group VI would constitute an undue burden, since the searches are entirely different and not coextensive, the classifications are different and the subject matter divergent.

Inventions I-III, V-VI, and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are not disclosed as used together. Invention group VII is a non-human transgenic animal which overexpresses at least one gene from the FSHD region. The methods of groups I-III, and V-VI have designs that are not compatible with

eachother. Groups I-III are methods of identifying compounds that bind to D4Z4, increase expression of D4Z4 recognition complex, or compounds that increase the interaction between D4Z4 and a recognition element. Group VII is to a transgenic that overexpresses one of the FSHD genes which have nothing to do with the D4Z4 sequence. Groups V-VI are methods of treating a subject having FSHD by administration of a compound and group VI is method of identifying subjects at risk for having FSHD. The transgenic would not be useful with either method.

Inventions VII and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the method can be used to determine whether a treatment is effective in an APP overexpressing non-human animal model of Alzheimer's disease.

Furthermore, within groups I, 4, 6, and 7 restriction to one of the following inventions is required under 35 USC 121:

The inventions are directed to a 4Q35 gene. The claims encompass several structurally unrelated genes in the region identified as being related to FSHD. For instance, absent evidence to the contrary the genes have different sequences and code for structurally and functionally different proteins called FRG1, FRG2, and ANT1.

Applicant is advised that this is not a requirement to elect a species. Rather, this is a second restriction requirement superimposed upon the

requirement to elect from groups I-VII. In order to be fully responsive, Applicant must elect one group from I-VII and should Applicant elect group I, IV, VI, or VII, one gene from the 3 listed above from within the elected group is also required.

Furthermore, within groups 3 and 5 restriction to one of the following inventions is required under 35 USC 121:

The inventions are directed D4Z4 binding components. The claims encompass several structurally and functionally unrelated proteins called YY1, HMGB2, and nucleolin.

Applicant is advised that this is not a requirement to elect a species. Rather, this is a second restriction requirement superimposed upon the requirement to elect from groups I-VII. In order to be fully responsive, Applicant must elect one group from I-VII and should Applicant elect group III, or V, one recognition component from the 3 listed above is also required.

In re Ochiai

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.
In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable,

the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Steven Standley whose telephone number is **(571) 272-3432**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on **(571) 272-0867**.

The fax number for the organization where this application or proceeding is assigned is **703-872-9306**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see **http://pair-direct.uspto.gov**. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

Steve Standley, Ph.D.
8/18/06

DAVID S. ROMEO
PRIMARY EXAMINER